UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P O Box 1450 Alexandria, Virgima 22313-1450 www.usplo.gov

DATE MAILED: 08/30/2010

NOTICE OF ALLOWANCE AND FEE(S) DUE

23364 7590 08/30/2010 BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314-1176 EXAMINER
YU, MELANIE J

ART UNIT PAPER NUMBER

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/517,322	12/15/2005	Per Mansson	MANS3010/REF	3648	

TITLE OF INVENTION: COATED METAL SURFACE ON SOLID SUPPORT FOR ANALYTE DETECTION BY DISPLACEMENT

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	11/30/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION NO THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and I/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

appropriate. All further indicated unless correct maintenance fee notifica	correspondence includir ed below or directed oth tions.	ng the Patent, advance on herwise in Block 1, by (a	rders and notification of a) specifying a new corr	maintenance fees v espondence address	vill be and/or	mailed to the current r (b) indicating a sepa	correspondence rate "FEE ADI	address as DRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)				Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.				
625 SLATERS I FOURTH FLOO)R	72010	11	Cer	tificate	e of Mailing or Trans s) Transmittal is being ficient postage for fire ISSUE FEE address I) 273-2885, on the d	denovited with	the United in envelope g facsimile low.
ALEXANDRIA	, VA 22314-1176						(Dep	ositor's name)
			L					(Signature)
								(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTO	R	ATTO	RNEY DOCKET NO.	CONFIRMATI	ON NO.
10/517,322 TITLE OF INVENTION	12/15/2005 E: COATED METAL SU	RFACE ON SOLID SUF	Per Mansson PORT FOR ANALYTE	DETECTION BY I		AANS3010/REF CEMENT	3648	
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUI	PREV. PAID ISSU	E FEE	TOTAL FEE(8) DUE	DATE	DUE
nonprovisional	YES	\$755	\$300	\$0		\$1055	11/30/	2010
EXAM	IINER	ART UNIT	CLASS-SUBCLASS	7				
YU, ME	LANIE J	I64I	436-518000	_				
"Fee Address" ind PTO/SB/47; Rev 03- Number is required. 3. ASSIGNEE NAME A	ND RESIDENCE DATA less an assignee is ident h in 37 CFR 3.11. Comp			gle firm (having as a agent) and the nam corneys or agents. If e printed. ype) patent. If an assign assignment.	membes of u no nan	p to p to see is 3dentified below, the d	ocument has be	en filed for
Please check the appropr	iate assignee category or	categories (will not be pr	inted on the patent):	Individual C	orporati	ion or other private gro	oup entity 🗖 G	iovernment
Advance Order -	wo small entity discount p	permitted)	b. Payment of Fee(s): (PI A check is enclosed Payment by credit c The Director is herel overpayment, to Dep	ard. Form PTO-2038	is atta	iched.		lit any this form).
	s SMALL ENTITY state	is. See 37 CFR 1.27.	☐ b. Applicant is no lo					
NOTE: The Issue Fee an interest as shown by the	d Publication Fee (if req records of the United Sta	uired) will not be accepte tes Patent and Trademark	d from anyone other than Office.	the applicant; a reg	stered.	attorney or agent; or th	e assignee or ot	her party in
Authorized Signature				Date				
Typed or printed name				Registration N	lo			
This collection of inform an application. Confiden submitting the complete this form and/or suggest Box 1450, Alexandria, V Alexandria, Virginia 223	nation is required by 37 C tiality is governed by 35 d application form to the ions for reducing this but 'irginia 22313-1450. DC k13-1450.	FR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the ONOT SEND FEES OR	on is required to obtain or 1.14. This collection is of depending upon the indee Chief Information Offi COMPLETED FORMS	retain a benefit by stimated to take 12 ividual case. Any co cer, U.S. Patent and IO THIS ADDRES:	he pub minute mmen Trader S. SEN	lic which is to file (and is to complete, includir is on the amount of ti- nark Office, U.S. Dep D TO: Commissioner	by the USPTO g gathering, pre you require i artment of Com for Patents, P.O.	to process) paring, and to complete merce, P.O. . Box 1450,

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P O Box 1450 Alexandria, Virgima 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/517,322	12/15/2005	Per Mansson	MANS3010/REF	3648		
23364 75	90 08/30/2010		EXAM	INER		
BACON & THOMAS, PLLC			YU, MELANIE J			
625 SLATERS LA			ART UNIT	PAPER NUMBER		
FOURTH FLOOR ALEXANDRIA, VA 22314-1176			1641 DATE MAII ED: 08/30/2010			

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 285 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 285 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/517.322 MANSSON ET AL. Notice of Allowability Examiner Art Unit MELANIE YU 1641 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. 1. This communication is responsive to applicant's appeal brief filed 29 June 2010. The allowed claim(s) is/are 1-6 and 8-18. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). b) ☐ Some* c) ☐ None of the: a) 🔯 All 1. A Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. | Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date Information Disclosure Statements (PTO/SB/08). 7. X Examiner's Amendment/Comment Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit 8. X Examiner's Statement of Reasons for Allowance of Biological Material 9. ☐ Other .

Application/Control Number: 10/517,322 Page 2

Art Unit: 1641

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes
and/or additions be unacceptable to applicant, an amendment may be filed as provided
by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be
submitted no later than the payment of the issue fee.

The application has been amended as follows:

Previously withdrawn claims 8-11 have been rejoined with the allowed claims.

REASONS FOR ALLOWANCE

- 1. The following is an examiner's statement of reasons for allowance: the prior art fails to teach a protein layer bound to low molecular weight antigens with a linker molecule having functional end groups connected with an aliphatic hydrocarbon chain of 1, 2 or 3 carbon atoms, wherein the antigens are reversibly bound to antibodies specific for the antigens.
- 2. Sakai et al. (Sensor and Actuators) teach a morphine antigen connected to a BSA protein using a linker that contains 4 carbon atoms, but fail to teach a carbon linker having 1, 2 or 3 atoms. Sakai et al. also teach that when 4 carbon atoms are used in the linker, the antigens are not reversibly bound to antibodies specific for the antigens. Therefore based on the teaching of Sakai et al., it would not have been obvious to use a linker shorter than 4 carbons because one having ordinary skill would not have expected a reversible binding between the antibody and antigen.
- Jacobs et al. (US 6,905,816) teach a bifunctional linker having 0 to 50 carbon atoms, and specifically teaches linkers that have 2 carbon atoms. However, Jacobs et

Application/Control Number: 10/517,322

Art Unit: 1641

al. teach many different linkers with a wide range of number of carbon atoms and do not specifically point to a linker having 1, 2 or 3 carbon atoms. Furthermore, Jacobs et al. do no teach the linker being between an antigen and a protein.

4. Miura et al. (US 2002/0009812) teach a morphine-BSA conjugate, which is an antigen attached to a protein through a linker, but do not specifically teach the recited bifunctional linker and an aliphatic carbon chain that contains 1, 2 or 3 carbon atoms.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/517,322 Page 4

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/ Primary Examiner, Art Unit 1641